AUG 07 2009

K092343

Section 5

510(k) Summary

General Provisions	Submitter Name: Address: Telephone Number: Fax Number: Contact Person: Date of Preparation: Registration Number:	Merit Medical Systems, Inc. 1600 West Merit Parkway South Jordan, UT 84095 (801) 208-4795 (801) 253-6996 Glenn Norton July 30, 2009 1721504
Subject Device	Trade Name: Common/Usual Name: Regulation Name: Manufacturer:	*EN* Snare® Endovascular Snare System Intravascular snare and catheter Device, Percutaneous Retrieval Merit Medical Systems, Inc
Predicate Device	Trade Name: Common/Usual Name: Regulation Name: Manufacturer: Premarket Notification: Decision Date:	*EN* Snare® Endovascular Snare System Intravascular snare and catheter Device, Percutaneous Retrieval Medical Device Technologies, Inc K021606 05/31/2002
Classification	Class II Embolectomy Catheter 21 CFR § 870.5150, 74 MMX Division of Cardiovascular Devices	
Intended Use	The EN Snare Endovascular Snare and Catheter is intended for use in the cardiovascular system or hollow viscous to retrieve and manipulate foreign objects. Manipulation procedures include indwelling venous catheter repositioning, indwelling venous catheter fibrin sheath stripping, and central venous access venipuncture procedure assistance.	

Device Description	The *EN* Snare® Endovascular Snare System consists of four individual components: snare; catheter; snare introducer; and torque device. The snare is comprised of 3 cable loops which are secured to a shaft wire. The construction of the snare enables it to be introduced through a catheter and manipulated by use of an external torque device. A snare introducer is also included for optional back-end loading of the snare into a pre-placed catheter.
Technological Characteristics	There are no technological differences between the subject and predicate devices. The system is manufactured with identical design, materials and processes as that of the currently marketed *EN* Snare® Endovascular Snare System.
Safety & Performance Tests	No safety or performance testing is required to establish the safety and efficacy of the subject device.
Summary of Substantial Equivalence	The EN Snare device built by Merit is substantially equivalent to the EN Snare device legally marketed by MD Tech via 510(k) K021606, due to identical intended use, design specifications, material specifications, manufacturing specifications and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-609
Silver Spring, MD 20993-0002

AUG 07 2009

Merit Medical Systems, Inc.
c/o Glenn Norton
1600 West Merit Pkwy.
South Jordan, UT 84095

Re: K092343
Trade/Device Name: EN Snare Endovascular Snare System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II (two)
Product Code: MMX
Dated: July 30, 2009
Received: August 3, 2009

Dear Mr. Norton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4

Indications for Use Statement

510(k) Number (if known): K092343

Device Name: ***EN* Snare® Endovascular Snare System**

Indications for Use:

The EN Snare Endovascular Snare and Catheter is intended for use in the cardiovascular system or hollow viscous to retrieve and manipulate foreign objects. Manipulation procedures include indwelling venous catheter repositioning, indwelling venous catheter fibrin sheath stripping, and central venous access veni-puncture procedure assistance.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Volmes

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K092343